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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,847	12/05/2003	William Alston	53291-US-CNT	8316

1095 7590 07/30/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
ALI, SHUMAYA B	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
07/30/2009	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM ALSTON

Appeal 2008-002586[1]
Application 10/729,847
Technology Center 3700

Decided: July 30, 2009[2]

Before TONI R. SCHEINER, DONALD E. ADAMS, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

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[1] Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.) is the real party in interest (App. Br. 2).

[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an aerosolization apparatus. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

Claims 1-20 are pending and on appeal (App. Br. 2). Claims 1 and 10, the independent claims, are representative and read as follows:

> 1. An aerosolization apparatus comprising:
> a body defining an inlet opening, an outlet opening, and an aerosolization chamber between the inlet opening and the outlet opening,
> wherein the aerosolization chamber is adapted to receive an elongated receptacle containing a pharmaceutical formulation and wherein the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis passing through the outlet opening when air or gas flows through the body.
>
> 10. An aerosolization apparatus for delivering an aerosolized pharmaceutical formulation to a user's respiratory tract, the apparatus comprising:
> a body defining an inlet opening, an outlet opening, and an aerosolization chamber between the inlet opening and the outlet opening,
> wherein the aerosolization chamber is adapted to receive an elongated receptacle containing a pharmaceutical formulation and wherein the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis parallel to an inhalation direction when the user inhales to cause air or gas to pass through the body.

The Examiner cites the following documents as evidence of unpatentability:

Dean	US 4,249,526	Feb. 10, 1981
Chiprich	US 5,614,217	Mar. 25, 1997

The following rejections are before us for review:

Claims 1-7, 10-17, and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dean (Ans. 3-6).

Claims 8 and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dean (Ans. 6-7).

Claims 9 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dean in view of Chiprich (Ans. 7-8).

ANTICIPATION

ISSUE

The Examiner finds that Dean discloses an aerosolization apparatus that has a body, inlet and outlet openings, and an aerosolization chamber adapted to receive an elongated receptacle containing a pharmaceutical composition (Ans. 4-5). The Examiner further finds that the elongated receptacle in Dean's apparatus "rotates . . . end-over-end about an axis substantially orthogonal to an axis passing through the outlet opening when air or gas flows through the body (2-fold axis of symmetry reads on end-over-end, see col.4 lines 32-38, figs.3 and 4)" (Ans. 4).

Appellant contends that, contrary to the Examiner's finding, Dean's Figures 1 and 2 show "a receptacle (24) in the aerosolization chamber (15) of Dean et al rotates about an axis that is parallel to the axes passing through the cutlet opening (5) of Dean" (App. Br. 4). Thus, Appellant argues, Dean

"does not disclose a chamber wherein a receptacle would rotate about an axis that is *orthogonal* to the axis of the outlet opening. Accordingly, Dean et al does not anticipate claim 1" (*id.*). Appellants make the same contention with respect to the corresponding limitation in claim 10 (*id.* at 4-5).

In view of the positions advanced by Appellant and the Examiner, the issues with respect to this rejection are:

1. Did the Examiner err in finding that Dean's apparatus meets the limitation in claim 1 requiring the aerosolization chamber to be configured such that "the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis passing through the outlet opening when air or gas flows through the body?"
2. Did the Examiner err in finding that Dean's apparatus meets the limitation in claim 10 requiring the aerosolization chamber to be configured such that "the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis parallel to an inhalation direction when the user inhales to cause air or gas to pass through the body?"

FINDINGS OF FACT ("FF")

1. Appellant's Figure 1A, reproduced below, shows an embodiment of the claimed invention "in an initial position" (Spec. 4):

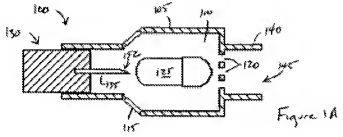


Figure 1 shows aerosolization apparatus 100, which "comprises a housing 105 defining a chamber 110 having one or more air inlets 115 and one or more air outlets 120. The chamber 110 is sized to receive a receptacle 125 which contains an aerosolizable pharmaceutical formulation" (Spec. 5).

Also seen in Figure 1A are:

> An opening mechanism 130 [which] comprises an opening member 135 that is moveable within the chamber 110. Near or adjacent the outlet 120 is an end section 140 that may be sized and shaped to be received in a user's mouth or nose so that the user may inhale through an opening 145 in the end section 140 that is in communication with the outlet 120.

(*Id.*)

2. Appellant's Figure 1C is reproduced below:

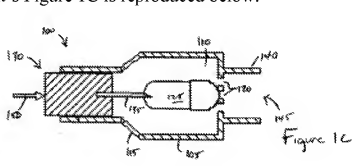


Figure 1C shows that, as force 150 is applied to opening mechanism 130, opening member 135 "is advanced to . . . extend into the wall of the receptacle 125, as shown in Figure 1C. The opening member may comprise one or more blunt or sharp tips 152 that contact the receptacle 125 in a manner that provides an opening into the receptacle 125" (Spec. 6).

3. Appellant's Figure 1D is reproduced below:

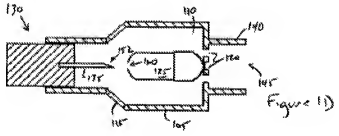


Figure 1D shows opening mechanism 130 in a retracted position after deployment, "leaving an opening 160 through the wall of the receptacle 125 to expose the pharmaceutical formulation in the receptacle 125" (Spec. 6).

4. Appellant's Figure 1E is reproduced below:

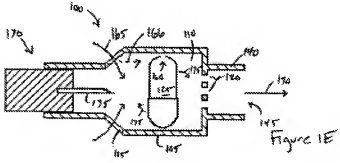


Figure 1E shows gas flowing through an inlet 115 as shown by arrows 165. "The flow of air causes the pharmaceutical formulation to be aerosolized. When the user inhales 170 through the end section 140 the aerosolized pharmaceutical formulation is delivered to the user's respiratory tract" (Spec. 6).

> As can be seen in Figure 1E, the chamber 110 of the aerosolization apparatus 100 is shaped so that the receptacle 125 rotates within the chamber 110. The airflow is designed so that the receptacle 125 rotates in the direction of the arrows 175, that is in an end-over-end manner. The rotation is substantially about an axis that is substantially orthogonal to the inhalation direction 170 and/or to the direction through the outlet 120.

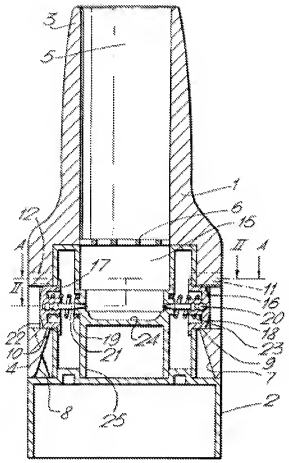
(*Id.* at 7.)

5. Thus, when the elongated receptacle 125 rotates about an axis substantially orthogonal to the inhalation direction and/or to the direction through the outlet 120, the receptacle essentially tumbles such that one end of the receptacle moves toward the outlet opening, and one end moves away from the outlet, as shown by arrows 175.

6. Dean discloses "an inhalation device for powdered medicaments contained initially in a container, which device is provided with means for locating the container in a position to be opened and appropriate opening means for the container" (Dean, col. 1, ll. 30-34).

7. Figure 1 of Dean, reproduced below, "is a longitudinal cross-section through a device of [Dean's] invention (*id.* at col. 3, ll. 39-40):

Fig.1.



Dean's Figure 1 shows upper housing member 1 "and a lower housing member 2 adapted to engage therewith. . . . Extending through upper housing member 1 is an air passageway 5, which is interrupted by a coarse sieve 6. Upper end 3 of housing member 1 is adapted for insertion into the mouth" (*id.* at col. 3, ll. 58-65).

8. Figure 3 of Dean, reproduced below, is a "transverse cross-section[] through the device of FIG. 1 along the line A--A, . . . showing the orientation of the housing members when the device is in use" (*id.* at col. 3, ll. 43-46):

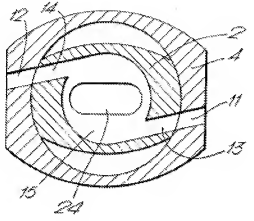


Fig. 3.

Dean's Figure 3 shows how the upper and lower housings align, such that when the device is in use, air inlets 11 and 12 communicate with passageways 13 and 14 to allow air to pass into aerosolization chamber 15 (*see id.* at col. 4, ll. 39-44).

9. Dean discloses that when the device is to be used, "a capsule is placed in depression 24. In position, the crowns of the capsule register with the piercing pins 20 and 21" (*id.* at col. 4, ll. 16-18; *see also* Figure 1).

When the upper housing member 1 is properly placed onto lower housing member 2, "push buttons 16 and 17 are depressed against the bias of springs 18 and 19 by cam surfaces 7 and 8, and piercing pins 20 and 21 pierce the crowns of the capsule," after which the pins retract (*id.* at col. 4, ll. 21-24).

10. Dean discloses that, once the capsule has been pierced and pins retracted:

> Mouthpiece 3 is then placed in the mouth and air is sucked through passageway 5. The air enters the housing through inlets 11 and 12 and passes into swirl chamber 15, dislodging the capsule from depression 24 and causing it to rotate about its 2-fold axis of symmetry. This movement causes the medicament to escape through the holes pierced in the crowns

> of the capsule and become entrained in the airstream to be carried into the mouth.

(*Id.* at col. 4, ll. 28-36.)

11. Thus, as seen by the configuration of Dean's swirl chamber 15, when the user's inhalation draws an airstream into the chamber through passageways 13 and 14, the capsule does not rotate such that one end of the receptacle moves toward the device's outlet opening 3, and one end moves away from the outlet. Rather, because of the orientation of the swirl chamber, the capsule rotates such that its ends remain essentially the same distance from the device's outlet opening.

PRINCIPLES OF LAW

It is well settled that, for a reference to anticipate a claim "[e]very element of the claimed invention must be literally present, *arranged as in the claim*." *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (emphasis added).

During examination, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The Examiner must therefore "determine[] the scope of claims in patent applications *not solely on the basis of the claim language*, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'"

Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed.Cir.2005) (emphasis added) (quoting *In re American Academy Of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

To establish that a reference inherently discloses a specific limitation, the Examiner may refer to extrinsic evidence showing that the descriptive matter missing from the reference is necessarily present in the reference's disclosure. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

Thus, the Examiner cannot establish inherency merely by demonstrating that the asserted limitation is probable or possible. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981). "If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient." *Id.* (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939)).

ANALYSIS

We agree with Appellant that the Examiner erred in finding that Dean's apparatus meets the limitation in claim 1 requiring the claimed device's aerosolization chamber to be configured such that "the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis passing through the outlet opening when air or gas flows through the body," and also erred in finding that Dean's apparatus meets the corresponding limitation in claim 10.

As discussed above, the Specification clarifies that when the elongated receptacle in the aerosolization chamber rotates end-over-end

about an axis substantially orthogonal to the inhalation direction and/or to the direction through the outlet, as recited in claims 1 and 10, the receptacle essentially tumbles such that one end of the receptacle moves toward the outlet opening, and one end moves away from the outlet, as shown by arrows 175 in Figure 1E (*see* FF 4, 5). In contrast, because of the configuration of Dean's swirl chamber 15, when a user's inhalation draws an airstream into the chamber through passageways 13 and 14, the capsule rotates such that its ends remain essentially the same distance from the device's outlet opening (*see* FF 8, 10, and 11).

We therefore do not agree with the Examiner that Dean's device is configured such that the capsule in the aerosolization chamber rotates end-over-end about an axis substantially orthogonal to the inhalation direction and/or to the direction through the outlet, as recited in claims 1 and 10.

Nor do we agree with the Examiner that Dean's apparatus is identical to Appellant's. As is evident from comparing Appellant's figures and Dean's figures, the inlets of Dean's swirl chamber are configured to cause the capsule to rotate *about* the device's longitudinal axis, whereas the embodiment shown in Appellant's Figure 1E has inlets configured to cause the capsule to rotate *along* the device's longitudinal axis (*compare* FF 4 to FF 7, 8). Thus, while it may be true that the claims' functional language is relatively broad, we are not persuaded that Dean's device is structurally indistinguishable from the claimed device, given that the prior art device and the claimed device are configured to rotate the capsule in different directions.

The Examiner hypothesizes that, during inhalation, "it is likely that a user may block one of the air inlet openings [of Dean's device]. Therefore,

when the user holds the inhaler such that he/she covers one of the inlet openings (11), inhalation suction force would cause air to enter through the other inlet (12)" (Ans. 10).

The Examiner urges that air "coming in from only one inlet would turn/rotate the receptacle toward the direction of the airflow/outlet opening" (*id.*). Thus, the Examiner argues, "a receptacle that is lifted and turned from a position perpendicular to the outlet opening to a direction of the outlet opening would inherently acquire[] a rotational axis that is orthogonal to the axis of the outlet opening" (*id.* at 10-11).

The Examiner further urges that the claimed rotational limitation is merely an intended use of the apparatus, and that Dean's "is fully capable of meeting such indented use recitation" (*id.* at 11). Specifically, the Examiner notes, Dean "never stated that his receptacle must meet certain size. The receptacle rotational axis would depend on the size of the receptacle as well as the chamber" (*id.*).

Thus, the Examiner argues, "a receptacle small enough, say for example, one third the size of the receptacle depicted in figure 2 of Dean et al., can be adapted to the chamber of Dean et al., which will provide the receptacle with enough space to rotate at any axis including an axis that is orthogonal to the outlet opening" (*id.*).

We do not find the Examiner's arguments persuasive. We agree, as noted above, that if the "disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient" to establish inherency. *In re Oelrich*, 666 F.2d at 581 (quoting *Hansgirg v. Kemmer*, 102 F.2d at 214)). However, it is

well settled that the Examiner cannot establish inherency merely by demonstrating that the asserted limitation is probable or possible. *Oelrich*, 666 F.2d at 581.

We also note that it is acceptable for the Examiner to use extrinsic evidence to support a finding of inherency. *Continental Can*, 948 F.2d at 1268. In the instant case, however, the Examiner has not provided any evidence supporting the assertions that using a sufficiently small capsule in Dean's device, or using Dean's device with one of the inlets blocked, would result in the capsule rotation required in claims 1 and 10.

In sum, we agree with Appellant that the Examiner has failed to make a prima facie case of anticipation with respect to claims 1 and 10. We therefore reverse the Examiner's rejections of those claims, and their dependents, as anticipated by Dean.

OBVIOUSNESS

Claims 8 and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dean (Ans. 6-7).

Claims 8 and 18 ultimately depend from claims 1 and 10, respectively, and require the receptacle to be present in the device in the form of a capsule that contains a "powder pharmaceutical formulation [which] comprises particles having a mass median diameter less than 10 μm." (Claims 8 and 18.)

The Examiner finds that the mass median diameter of a pharmaceutical powder "can be made smaller or larger to respectively increase or decrease the absorbent nature of tissue, and tissue can vary from patient to patient[]" (Ans. 7). Therefore, the Examiner concludes, "it would

have been obvious to one of ordinary skills in the art at the time the invention was made to manipulate the mass median diameter of pharmaceutical formulation particles because doing so would have allowed treatment depending on patient's tissue absorbent efficiency" (*id.*).

We reverse this rejection as well. Claims 8 and 18 depend from claims 1 and 10 and also require the device to be configured in the manner recited in claims 1 and 10. The Examiner points to no disclosure in Dean, or any other rationale, that remedies the deficiencies of Dean discussed above with respect to claims 1 and 10. Thus, on the current record, Dean fails to teach or suggest all of the limitations of claims 8 and 18.

Claims 9 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dean in view of Chiprich (Ans. 7-8).

Claims 9 and 19 ultimately depend from claims 1 and 10, respectively, and require the powder in receptacle to have "a moisture content below 5% by weight." (Claims 9 and 19.) The Examiner concedes that Dean fails to meet this limitation, and cites Chiprich to meet it (*id.* at 8).

However, the Examiner points to no disclosure in Dean or Chiprich, or any other rationale, that remedies the deficiencies of Dean discussed above with respect to claims 1 and 10. We therefore reverse the Examiner's rejection of claims 9 and 19 as being obvious in view of Dean and Chiprich.

SUMMARY

We reverse the Examiner's rejection of claims 1-7, 10-17, and 20 under 35 U.S.C. § 102(b) as being anticipated by Dean.

We also reverse the Examiner's rejection of claims 8 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Dean.

We also reverse the Examiner's rejection of claims 9 and 19 under

35 U.S.C. § 103(a) as being unpatentable over Dean in view of Chiprich.

REVERSED

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